

**REMARKS**

Claims 1-42, and 51 were cancelled, and claims 43-47, and 49 were withdrawn. Claims 48, 50 and 52-54 are currently pending. By this amendment, claims 48 and 49 are amended.

The amendments replace the term "reducing" with the term "preventing." Support for the amendments are found on pages 12-13 and table 1 of the Specification.

Reconsideration is respectfully requested in view of the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action. Reconsideration is respectfully requested in light of the above amendments and the following remarks.

**Rejections Under 35 U.S.C. § 112, First Paragraph, New Matter, New Rejection**

Claims 48, 50, 52-54 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the Examiner objects to the term "at least" in conjunction with the percentages of trehalose specified in claims 48 and 52-54. Applicants respectfully traverse.

Examples 1-3 (pages 9-13) disclose the effectiveness of 10% and 15% trehalose in preventing aggregation following rehydration of a dehydrated sample and during freezing as specified in independent claims 48 and 49. Table 1 (page 12) shows the effectiveness of 30% trehalose in preventing aggregation.

Dictionaries are used by the court to aid in the task of determining meanings that would have been attributed by those of skill in the relevant art. See *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372, 57 USPQ2d 1087, 1089 (Fed. Cir. 2000) ("A dictionary is not prohibited extrinsic evidence, and is an available resource of claim construction."). Dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms. *Texas Digital Systems, Inc. v. Telegenix, Inc.* 308 F.3d 1193, 1202; 64 U.S.P.Q.2d (BNA) 1813 (2002) (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*,

299 F.3d 1313, 1325, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) ("The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including . . . dictionaries and treatises . . ." (internal citations omitted)).

The ordinary dictionary meaning of the term "at least" is "at the minimum" (*see* Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> ed., Merriam-Webster Inc. Springfield, Mass. (USA)). The Specification explicitly discloses the effectiveness of trehalose at the minimum concentrations of 10%, 15% and 30%, as discussed above. Therefore, Applicants respectfully submit that specifying the minimal amounts of trehalose required for effectiveness in terms of "at least" 10%, 15% or 30% in claims 48, 50, 52-54 is proper as it would have been understood as minimum concentrations by one of skill in the art. Withdrawal of this ground for rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement, New Rejection**

Claims 48, 50, 52-54 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

(i) Specifically, the Examiner asserts that the Specification discloses prevention of aggregation and not reduction of previously aggregated particles.

In response, the Applicants amend independent claims 48 and 49 to specify "preventing aggregation of particulates" instead of reducing aggregation. Applicants state that the term "preventing" is not intended to be interpreted as an absolute term as the level of prevention is relative to the concentration of trehalose used.

In light of the amended claim language, Applicants respectfully request withdrawal of this ground for rejection of claims 48, 50, 52-54.

(ii) The Examiner also states that it is unpredictable that 10% trehalose specified in claims 48 and 50 is sufficient to prevent aggregation. The Examiner points to the lack of effectiveness at 7.5% shown in Table 1 of the Specification.

Applicants note that claims 48 and 50 are directed to "preventing aggregation during

dehydration and rehydration of particulates in suspension." Example 1 (pages 9-10) discloses the prevention of aggregation of particulate suspensions by "10% w/v trehalose" during drying and subsequent rehydration. (page 9, lines 13-23).

In contrast, Example 3, Table 1 and Figure 3 show that trehalose is not effective at preventing aggregation at 7.5% but effective at 15% during vacuum drying and freezing (not rehydration).

Therefore, Applicants submit that 10% trehalose specified in claims 48 and 50 is enabled by the Specification and is not an unpredictable value. Applicants respectfully request withdrawal of this ground for rejection of claims 48 and 50.

**CONCLUSION**

In light of the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 263742000201.

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Respectfully submitted,

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